REMARKS

Claims 5-7 have been amended. Claims 1, 4-8, 10, 43-45, 50, 56, and 57 are pending in the instant application. No new matter has been added as a result of the above-described amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

1. Rejection of claims 1, 4-8, 10, 11, 43-45, 50, 56, and 57 under 35 U.S.C. § 101

The Office Action asserts a rejection of claims 1, 4-8, 10, 11, 43-45, 50, 56, and 57 under 35 U.S.C. § 101. The Action alleges that the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. Applicant traverses this rejection.

Applicant contends that the instant application contains an assertion of a specific and substantial utility for the claimed invention that would be credible to one of ordinary skill in the art. The instant application teaches nucleotide sequences encoding amino acid sequences for two isoforms of TGF–β–R polypeptide (Figures 1A-1B and 2A-2B). The instant application also discloses that a search of the Non-Redundant Protein database, using the amino acid sequence of isoforms 1 or 2 of human TGF–β–R polypeptide, indicated that these proteins share the greatest degree of similarity with human and murine Growth Differentiation Factor-3 (GDF-3), and most significantly, that the location and spacing pattern of cysteine residues (which play an important role in GDF-3 structure) is conserved between TGF–β–R polypeptide and GDF-3 (page 80, lines 22-26).

Based on the knowledge in the art at the time the instant application was filed, Applicant contends that one of ordinary skill in the art would recognize that TGF–β–R polypeptide is a member of the TGF–β family of proteins. The Action states that members of the TGF-β family have diverse functions. The Action asserts that "identification of a protein as a member of this family does not endow it with a utility." Applicant points out that TGF-β-R is related to a sub-family of the TGF-β superfamily, namely the bone morphogenetic proteins (BMPs).

Specifically, as discussed in the Applicant's Response dated December 29, 2003, TGF-β-R shares the greatest degree of similarity with human and murine Growth Differentiation Factor-3 (GDF-3). The Response also pointed out that the location and spacing pattern of cysteine residues (which play an important role in GDF-3 structure) is conserved between TGF–β–R polypeptide and GDF-3 (page 80, lines 22-26). GDF-3 is a bone morphogenetic protein (BMP). GDF-3 is described

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at www.ncbi.nlm.nih.gov/entrez/dispomim.cgi?id=606522. The BMPs are members of the highly conserved transforming growth factor-beta (TGF-β) superfamily.

One of skill in art will recognize that BMP signaling is important during development and growth. Based on the expression of human TGF–β–R mRNA in adult prostate, testis, and ovary, and fetal liver (page 81, lines 20-21), and the teaching that TGF–β–R polypeptide shares homology with GDF-3, one of ordinary skill in the art would recognize that the claimed molecules have a credible utility, for example, in regulating cell growth and development in prostate, testis, ovary, and/or liver.

Applicant contends that because the instant application contains an assertion of a specific and substantial utility for the claimed invention credible to one of ordinary skill in the art, the rejection under 35 U.S.C. § 101 should be withdrawn.

2. Rejections of claims 1, 4-8, 10, 43-45, 50, 56, and 57 under 35 U.S.C. § 112, first paragraph

The Office Action asserts a rejection of claims 1, 4-8, 10, 43-45, 50, 56, and 57 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention. The Action states that because the claimed invention is not supported by a specific and substantial asserted utility or a well-established utility, one skilled in the art would not know how to use the claimed invention.

Applicant has set forth above affirmative evidence that the asserted utility would be credible to one of ordinary skill in the art. Applicant contends that because the instant application contains an assertion of a specific and substantial utility for the claimed invention that one of ordinary skill in the art would find to be credible, this rejection should be withdrawn.

The Office Action also asserts a rejection of claims 1, 4-8, 10, 43-45, 50, 56, and 57 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement and written description for variants or fragments. The Action states that cancellation of claims 2 and 3 is not sufficient to overcome these rejections. However, Applicant points out that the pending claims do not have fragment language. The only variants encompassed by the claims must hybridize under the highly stringent conditions provided in amended claim 1(d). The specific conditions now recited in claim 1(d) are taught in the instant specification at page 16, lines 7-9. Applicant contends that it would not require undue

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experimentation for one of ordinary skill in the art to make and use such nucleic acid molecules, because doing so requires simple, routine hybridization experiment.

The Office Action also asserts a rejection of claims 1, 4-8, 10, 43-45, 50, 56, and 57 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description. As discussed above, the pending claims do not have fragment language. Variants as encompassed by claim 1(d) are well defined by the characteristic of hybridizing under the highly stringent conditions set forth in the claim as amended. With regard to the amendment to recite specific hybridization conditions (set forth in the application at page 16, lines 7-9), Applicant notes that the Federal Circuit has recently indicated that a claim that recites a genus of nucleotide sequences based on their hybridization properties "may be adequately described if [the claimed nucleic acid molecules] hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1327 (Fed. Cir. 2002). Applicants contend that in view of *Enzo Biochem, Inc.*, the nucleotide sequences recited in claim 1(d) are adequately described since the instant specification describes hybridization at 65°C in a buffer comprising 0.015 M sodium chloride and 0.0015 M sodium citrate or in a buffer comprising 0.015 M sodium chloride, 0.0015 M sodium citrate, and 50% formamide at 42°C as "highly stringent" (*see, e.g.*, page 16, lines 7-9). Applicants submit that in view of the explicitly-disclosed sequences and highly stringent hybridization conditions provided by the instant application, claim 1 satisfies the written description requirement of 35 U.S.C. § 112, first paragraph.

Applicant respectfully contends that rejections based on 35 U.S.C. § 112, first paragraph, have been overcome by amendment or traversed by argument, and request that the Examiner withdraw all rejections made on this basis.

3. Rejections of claims 5 and 6 under 35 U.S.C. § 101

Claims 5 and 6 are rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. Specifically, the Action points out that the claims do not require that the host cells are isolated. The claims have been amended to recite "isolated host cell," thereby overcoming this rejection.

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CONCLUSIONS

Applicant respectfully contends that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner Andres believes it to be helpful, she is invited to contact the undersigned representative by telephone at 312-913-0001.

Respectfully submitted,
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